K050255

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MAR 17 2005

510(k) Summary Statement for the
Gendex Orthoralix 8500 Panoramic Dental X-ray System

I. General Information

Submitter:	Gendex Dental Systems 901 West Oakton Street Des Plaines, IL 60018
Telephone:	(847) 640-4800 – Company number (847) 640-4924 – Contact person
Fax:	(847) 640-4970
Contact Person:	John R. Miller Director, Quality Assurance and Regulatory Affairs
Summary Preparation Date:	January 31, 2005

II. Names

Device Name:	Orthoralix 8500 Panoramic Dental X-ray System
Primary Classification Name:	90EHD – Extraoral Source X-ray System

III. Predicate Devices

- Gendex Orthoralix 9200
- Planmeca DIMAX2
- Gendex Orthoralix 9200 DDE
- Gendex GX-9000

IV. Product Description

The Orthoralix 8500 is a system for rotational panoramic radiography of the dento-maxillo-facial area. The system consists of:

- Column to be mounted to the wall
- Motor-driven overhead assembly with controls for patient postioning, setting of technique factors and radiographic projection geometry.
- Cassette drvie system with flat cassette for 15 x 30 cm film
- X-ray tubehead, with DC power supply
- Remote control box and handswitch

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During a panoramic exposure, the x-ray tubehead and cassette holder move around the patient's head. The beam from the x-ray tube is collimated by a slit diaphragm. The flat film cassette passes behind a secondary collimator, which blocks the radiation scattered from the patient. Patient positioning is simple, accurate and consistent by means of three postioning lasers, a bite guide and head stabilizers. During the exposure, the patient remains still while the motorized components rotate. All movements for the panoramic radiographic projection are performed by independent motors, which are microprocessor controlled.

Along wit the Standard Panoramic mode, the Orthoralix 8500 provides a special child projection, designed to further reduce radiation dosage to the child, and confining the image to the dentition.

V. Indications for Use/Rationale for Substantial Equivalence

The Orthoralix 8500 Panoramic Dental X-ray System is to be used as an extraoral source of x-rays for imaging of the dento-maxillo-facial area.

It share the same indications for use, similar materials, design, operational, and functional features and therefore is substantially equivalent to the predicate devices listed in Section II of this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Mr. John R. Miller
Director, Quality Assurance & Regulatory Affairs
Gendex Dental Systems
901 W. Oakton Street
DES PLAINES IL 60018

Re: K050255
Trade/Device Name: Orthoralix 8500 Panoramic Dental X-ray System
Regulation Number: 21 CFR §872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: February 2, 2005
Received: February 3, 2005

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): Not Assigned

Device Name: Orthoralix 8500 Panoramic Dental X-Ray System

Indications for Use:

The Orthoralix 8500 Panoramic Dental X-Ray System is to be used as an extraoral source of x-rays for imaging of the dento-maxilofacial area.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050255